wherein said first group of said daily dosage portions of said second stage consists of five of said daily dosage portions of said combination and wherein said second group of said daily dosage portions of said second stage consists of seventeen of said daily dosage portions of said combination; and

wherein respective amounts of said estradiol valerate in each of said daily dosage portions of said second stage are equal and respective amounts of said dienogest or said drospirenone in said daily dosage portions of said second group of said second stage are larger than those of said daily dosage portions of said first group of said second stage.

REMARKS

In response to the Notice of Abandonment dated November 18, 2003, applicants are filing an accompanying Petition to Revive in order to revive this abandoned application. The benefit of the priority date of the above-identified U.S. Patent Application is therefore claimed for the subject matter of new claim 16. This priority date is October 28, 1995, the filing date of 195 40 253.7-41, the priority document for U.S. Patent Application Ser. No. 08/738,314, the parent application for the above-identified Ser. No. 09/648,858.

I. New Claim 16

New claim 16 is based on only two regimens one involving estradiol valerate as the natural estrogen and dienogest as the gestogen (as in the original Declaration filed in the application) and the other involving estradiol valerate as the natural estrogen and drospirenone as the gestogen. Basis for estradiol valerate and the two gestogens is found on page 8, last line, to page 9, line 8, of the applicants' specification. Drospirenone is a C-21 gestogen, as described on page 9 of the specification.

The features of new claim 16 are supported by the disclosure in the specification and original claims of the above-identified U.S. Patent Application.

The regimen in general is divided up into a first, second, third and additional stages, in which only estradiol valerate is administered in the first and third stages and a placebo is administered in the additional stage. In the second stage estradiol valerate and either dienogest or drospirenone is administered. These features are fully supported by the disclosure on page 8 of applicants' specification.

However new claim 16 differs from the previous independent method claims in that each stage has a single definite number of days in it instead of a range of days. In the first, third and additional stages of claim 16 there are two daily dosage portions in each stage. Basis for these daily dosage portions is found in the lower limits for the ranges on page 8. In addition the second stage is

broken up into a first group of 5 daily dosages and a second group of 17 daily dosages, which is supported by the first four lines of the last paragraph on page 8 of applicants' specification.

The feature that the gestogen dosages in the second group are greater than the gestogen dosages in the first group of the second stage is also supported in the last paragraph of page 8 of applicants' specification. The basis for the other features including the equal dosages, e.g., in the first stage, is found in the examples in the applicants' specification.

Thus the subject matter of the new claim 16 has basis in the original disclosure in applicants' specification and claims.

II. Obviousness of New Claim 16 based on Prior Art

Claims 1 to 7 were rejected under 35 U.S.C. 103 (a) as obvious over Embase Abstract -272 in view of WPIDS abstracts -924 and -225 and all the references of record in U.S. Patent Application Ser. No. 08/738,314.

Amended claim 1 of U.S. Patent 6,133,251, which issued on Ser.No. 08/738,314, the parent application of the above-identified U.S. Patent Application, was allowed on the basis of the evidence in the Declaration filed with the amendment dated March 12, 2002. The results in the Declaration show that the method claimed in that claim 1 is more effective in preventing conception than that of the two DE references, but at the same time significantly reduces intercyclic bleeding.

However canceled claim 1 of the above-identified U.S. Patent Application was broader than the amended claim 1 of U.S. Patent 6,133,251, which eventually issued. This latter broad claim has now been canceled. New claim 16 claims two individual preferred embodiments, which were not *explicitly and expressly* covered by dependent claims of the issued patent and which are arguably much narrower than either claim 1 of the issued patent or the canceled claim 1.

It is respectfully submitted that the Declaration that was filed in the parent application and resulted in the issuance of U.S. Patent 6,133,251, provides an ample basis for allowance of new claim 16.

Although the regimen in the case of dienogest and estradiol valerate does differ from the regimen in the Declaration it is almost the same. The length of the first and additional stages differs by one day in the case of claim 16, but otherwise all features of new claim 16 "fit" the example of the invention on page 3 of the Declaration. Regarding the drospirenone embodiment, applicants find that that embodiment has similar improved bleeding and contraceptive behavior.

Thus it is respectfully submitted that the showing in the Declaration is commensurate with the scope of new claim 16 for two particularly preferred embodiments of the contraceptive preparation. The showing proves that the claimed contraceptive preparation of new claim 16 has unexpectedly improved properties in comparison to the closest prior art. See the "Response to Argument" on page 3 and 4 of the Office Action dated May 20, 2003.

For the foregoing reasons and because of the comparative experimental results filed in the Declaration filed in the parent application, it is respectfully submitted that new claim 16 should **not** be rejected under 35 U.S.C. 103 (a) as obvious over Embase Abstract -272 in view of WPIDS abstracts -924 and -225 and all the references of record in U.S. Patent Application 08/738,314.

III. Possible Double Patenting Rejection

Please note that a timely filed terminal disclaimer has already been filed in this application disclaiming that portion of the term of any patent that issues on the above-identified U.S. Patent Application that exceeds the term of U.S. Patent 6,133,251. This was acknowledged in the previous Office Action.

Should the Examiner require or consider it advisable that the specification, claims and/or drawing be further amended or corrected in formal respects to put this case in condition for final allowance, then it is requested that such amendments or corrections be carried out by Examiner's Amendment and the case passed to issue. Alternatively, should the Examiner feel that a personal discussion might be helpful in advancing the case to allowance, he or she is invited to telephone the undersigned at 1-631-549 4700.

In view of the foregoing, favorable allowance is respectfully solicited.

Respectfully submitted,

Michael J. Striker,

Attorney for the Applicants

Reg. No. 27,233